Questions and Answers

1. Q: What does the physician referral law prohibit?

1. A: The physician referral law (section 1877 of the Social Security Act) prohibits a physician from referring patients to an entity for a DHS, if the physician or a member of his or her immediate family has a financial relationship with the entity, unless an exception applies.

The law also prohibits an entity from presenting a claim to Medicare or to any person or other entity for DHS provided under a prohibited referral. Medicare does not pay for services provided as the result of a prohibited referral. Civil money penalties and other remedies may also apply under some circumstances. (01/04/2001)

2. Q: What are the DHS?

2. A: The categories of DHS are:

- **Clinical laboratory services.**
- **Physical and occupational therapy and speech-language pathology services.**
- **Radiology and certain other imaging services.**
- **Radiation therapy services and supplies.**
- **Durable medical equipment and supplies.**
- **Parenteral and enteral nutrients, equipment, and supplies.**
- **Prosthetics, orthotics, and prosthetic devices and supplies.**
- **Home health services.**
- **Outpatient prescription drugs.**
- **Inpatient and outpatient hospital services.**

(01/04/2001)

3. Q: Why is the government regulating the business aspects of a physician's practice?

3. A: The physician referral law was enacted to help protect the Medicare program from abuse. Studies by the HHS Office of the Inspector General and other governmental agencies have shown that referrals to entities with which physicians have a financial relationship encourage excessive use of those services, frequently resulting in higher costs to Federal health care programs. In certain cases, the American Medical Association considers the practices unethical. (01/04/2001)

4. Q: What is a referral?

4. A: In general, a referral means a request for, or the ordering of, a DHS by a physician. Also, a referral includes the establishment of a plan of care and certification or recertification of patients needs for any DHS for which payment

may be made under Medicare. A referral also includes a request for a consultation with another physician and any test or procedure ordered by the physician-consultant, except for certain services performed or supervised by a pathologist, radiologist, or radiation oncologist. In this rule, we explain that we do not consider that a physician has made a referral if the referring physician personally performs the DHS. (01/04/2001)

5. Q: What is a financial relationship?

5. A: A financial relationship is:

- **An ownership or investment interest by a physician or an immediate family member of the physician in an entity that furnishes DHS; or**
- **A compensation arrangement between a physician or an immediate family member of the physician and an entity that furnishes DHS.**

The law specifically covers both direct and indirect financial relationships. (01/04/2001)

6. Q: What is an indirect financial relationship?

6. A: In this final rule we explain that an indirect ownership or investment interest exists if, between the referring physician (or immediate family member) and the furnishing entity there is at least one intervening ownership or investment interest, and the chain of ownership or investment interests between the parties is unbroken. Also, the entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the physicians (or family members) ownership or investment interest in the furnishing entity.

An indirect compensation arrangement exists if (i) there is an unbroken chain of compensation arrangements, or a mix of ownership and compensation arrangements, between the physician (or family member) and the entity; (ii) the physicians aggregate compensation takes into account the volume or value of referrals generated by the physician for the furnishing entity; and (iii) the entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the physician is receiving indirect compensation.

These definitions substantially reduce the potential financial liability of hospitals and other entities providing DHS if they can show they neither knew of, nor had reason to suspect, an indirect relationship with the referring physician or his or her immediate family member. Under the proposed rule, a claim submitted by an entity would have been disallowed, even if the entity had no knowledge of the indirect financial relationship. (01/04/2001)

7. Q: What kinds of financial relationships are excepted from the prohibition?

7. A: The law includes exceptions that apply to very specific types of arrangements. Some of the exceptions apply to both ownership and compensation arrangements, while others apply to only one or the other. We have also created several new exceptions in Phase I under our rulemaking authority. These are described below. (01/04/2001)

8. Q: What is HCFA's general approach to the final rule?

8. A: We have substantially revised the proposed rule in response to the public comments to provide more flexibility. In general, we have interpreted the prohibition narrowly and the exceptions broadly. We have also divided the rulemaking process into phases. In Phase I we provide guidance on a majority of the Medicare-related issues raised in the public comments. Remaining provisions will be addressed in Phase II. (01/04/2001)

9. Q: Why will the final rules have comment periods?

9. A: Because we are making a number of changes to the provisions in the proposed rule, we think it is appropriate to give the public an opportunity to comment on the new provisions. (01/04/2001)

10. Q: Why is the effective date for all but one of the provisions in Phase I delayed for 1 year?

10. A: We have delayed the effective date to allow individuals and entities who are affected by the rule enough time to restructure their business arrangements to comply with Phase I where it proscribes conduct not previously prohibited. However, one provision does take effect 60 days after the date of publication in the Federal Register. In the proposed rule covering referrals for DHS, we had proposed replacing the physician certification requirements for home health services in section 424.22(d) with the physician referral provisions, since home health services are DHS. Phase I reflects this change.

Under the previous version of section 424.22(d), a physician with a significant financial relationship with a home health agency (HHA) could not certify or recertify a patients need for home health services. A physician was considered to have a significant ownership interest in an HHA if he or she owned 5 percent or more of the entity or had transactions with the HHA that amounted to more than $25,000 in a fiscal year. Phase I replaces these financial limits with the more flexible provisions in section 1877 of the Act. Physicians and HHAs will be able to take advantage of this change relatively soon.

Otherwise, the statute, in its entirety, remains in full force and effect with respect to all DHS listed in section 1877(h)(6) of the Act. Until the effective date of these new final regulations, the August 1995 final rule covering referrals for clinical laboratory services remains in full force and effect with respect to clinical

laboratory services referrals and claims for services. Any party or parties who do not comply with the provisions of the statute, the August 1995 final rule covering referrals for clinical laboratory services, or the provisions of Phase I of this rulemaking (when Phase I becomes effective one year from the date of publication in the Federal Register) are subject to all applicable penalties and sanctions, including those that appear in section 1877(g) of the Act. (Section 1877(g)(3) and (g)(4) sanctions are covered in the final rule issued by the Department's Office of the Inspector General (OIG) that was published at 60 FR 16580 on March 31, 1995.) (01/04/2001)

11. Q: How will Phase I affect Medicare beneficiaries access to health care?

11. A: The final rule should not affect access to health care. We have interpreted the prohibition on referrals narrowly and the exceptions broadly in large part to avoid interfering with beneficiary access. In many cases, the financial relationships between physicians and the entities that furnish services will fit within one of the exceptions. The rule also ensures that physicians and entities have alternative approaches in cases where the rule would restrict referrals under their current arrangements. In addition, we have exempted certain items and services to ensure that beneficiaries are not unnecessarily inconvenienced. We have also made changes in some of our definitions to ameliorate what may otherwise have been obstacles to obtaining Medicare services. (01/04/2001)

12. Q: How will the rule affect physicians?

12. A: Phase I should not have a significant effect on most physicians. Since we have interpreted the exceptions in this final rule more broadly than we did in the proposed rule, physicians should find it easier to comply with the law and regulations. In addition, we have finalized a general compensation exception that applies to almost any arrangements in which physicians receive payments that are fair market value for the items and services they provide to an entity, provided certain other criteria are met. Also, in response to many comments, we have established clear definitions and administratively simpler requirements wherever possible. We believe that these steps will go a long way in reducing any burden this rule will have on physicians or other providers of care. (01/04/2001)

13. Q: Which statutory provisions are covered in Phase I of the rulemaking?

13. A: Phase I interprets the general referral prohibition and exceptions that apply to both ownership and compensation relationships. In addition, Phase I includes almost all of the definitions that are used throughout section 1877, including the group practice definition and the definitions for each of the DHS. Phase I addresses a majority of the public comments. (01/04/2001)

14. Q: Which statutory exceptions apply to both ownership and compensation relationships and are addressed in Phase I?

14. A: There are four general exceptions that apply to both ownership and compensation arrangements. These exceptions apply to:

- **Physician services that are furnished by or under the personal supervision of another physician in the same group practice as the referring physician.**
- **In-office ancillary services.**
- **Services furnished to enrollees of prepaid plans.**
- **Additional financial arrangements that the Secretary determines do not pose a risk of program or patient abuse.**

We received the greatest number of comments on the in-office ancillary services exception. (01/04/2001)

15. Q: What is the in-office ancillary services exception?

15. A: The in-office ancillary services exception allows physicians to refer DHS within their own practices, provided certain location, supervision, and billing requirements are met. Except for parenteral and enteral nutrients, equipment and supplies, and most durable medical equipment, referrals for all DHS may fit within this exception. Under the final rule, crutches, canes, walkers, and folding manual wheelchairs (to the extent necessary for a patient to safely leave the physicians office) may fall within this exception. In addition, this exception may apply to blood glucose monitors that are furnished by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient. (01/04/2001)

16. Q: How does Phase I change the criteria for the in-office ancillary services exception from those specified in the proposed rule?

16. A: Two of the most significant changes in the final rule involve the direct supervision requirement in this exception. We had proposed to interpret the direct supervision requirement to mean that a physician had to be present in the office during the time a DHS was being furnished. Instead, Phase I defines the supervision requirement as the same level of supervision that would already apply under all other Medicare payment and coverage rules for the specific service. In addition, we had proposed that independent contractor physicians in a group practice could not supervise in-office ancillary services; Phase I would allow them to supervise these services. These changes should provide practices with significantly more flexibility in furnishing DHS. (01/04/2001)

17. Q: Does Phase I allow unaffiliated physicians to share a DHS facility in the same building in which they practice (for example, a shared clinical laboratory)?

17. A: The in-office ancillary services exception may be used for services furnished in a shared facility that is owned by otherwise unaffiliated physicians if the services referred by each separate physician or group practice meet the in-office supervision,

location, and billing requirements. Phase I will allow shared facilities as long as the physicians or different groups that share the facility routinely provide their full range of services in the same building. (01/04/2001)

18. Q: How does this rule affect managed care arrangements?

18. A: A statutory exception at section 1877(b)(3) excludes services furnished to enrollees of Medicare prepaid health plans. This exception applies to:

- **Coordinated care plans offered by Medicare+Choice organizations;**
- **Health maintenance organizations and competitive health plans under section 1876 of the Social Security Act;**
- **Health care prepayment plans described in section 1833(a)(1)(A) of the Social Security Act;**
- **Qualified health maintenance organizations under section 1310(d) of the Public Health Service Act; and**
- **Certain prepaid Medicare managed care demonstration projects.**

In addition to the statutory exception described above, we have created a new compensation exception for bona fide risk-sharing arrangements between a managed care organization and a physician for services provided to enrollees of a health plan. This exception applies to compensation relationships between physicians and most employer group health and commercial managed care plans for items and services furnished to health plan members.

We have also revised the definition of entity to permit physician ownership of network-type health maintenance organizations, managed care organizations, provider-sponsored organizations, and independent practice associations. (01/04/2001)

19. Q: Are any other new exceptions created in Phase I?

19. A: We had proposed several new regulatory exceptions in the proposed rule. In response to comments, Phase I of the rulemaking modifies some of these exceptions and creates several additional regulatory exceptions covering compensation paid to a physician (and in some cases an immediate family member). In addition to the bona fide risk sharing exception described above, the new exceptions address compensation paid by academic medical centers; non-monetary compensation up to $300 (and medical staff benefits); and almost any compensation from an entity to a physician for the physician to furnish items or services, provided the compensation is consistent with fair market value for the items or services rendered. New exceptions also cover implants furnished in ambulatory surgical centers; erythropoietin (EPO) and other dialysis-related drugs provided by an end stage renal disease (ESRD) facility; preventive screening tests, vaccines, and

immunizations; compliance training programs; eyeglasses and contact lenses; and indirect compensation arrangements. (01/04/2001)

20. Q: Which statutory provisions will be covered in Phase II of the rulemaking?

20. A: To the extent necessary, all statutory exceptions not addressed in Phase I will be included in Phase II. Phase II will address comments received on exceptions that apply only to ownership and investment interests and comments on exceptions that apply only to compensation relationships. In addition, we will address comments on any remaining definitions. (01/04/2001)

21. Q: Does the length of the preamble to this rule mean that Medicare intends to micro-manage physician practices?

21. A: No. To the contrary, we believe that we have greatly decreased any micro-management that was implied by the proposed rule. In Phase I, we have interpreted the prohibition narrowly and the exceptions broadly, and have generally attempted to minimize the effects of the rule on potentially beneficial financial arrangements. Phase I minimizes the impact on many common physician group governance and compensation arrangements. While the preamble to the rule is lengthy in light of the approximately 12,800 comments we received on the proposed rule, the regulations text itself, the portion of the publication that ultimately will be included in the Code of Federal Regulations (CFR), is not long. The regulations text as it appears in the January 4, 2001 Federal Register is only 11 pages long. (01/04/2001)

22. Q: How will HCFA inform physicians about this regulation?

22. A: We will make speeches in various public forums and otherwise participate in meetings with organizations that represent physicians, providers, suppliers, and other members of the public. In addition, we will post a copy of the rule, the press release announcing publication of the final rule, and these Qs and As on the HCFA web site, www.hcfa.gov. (01/04/2001)

23. Q: How does Phase I affect the paperwork burden on physicians and other providers?

23. A: The rule minimizes both the administrative and paperwork burden on physicians, providers and suppliers. For example, the proposed rule would have required that every group of physicians wishing to qualify as a group practice annually attest in writing that the group has met certain criteria under the group practice definition. We have eliminated this attestation requirement. (01/04/2001)

24. Q: What are some of the other specific differences between Phase I and the January 1998 proposed rule?

24. A: In addition to some of the specific changes described above, Phase I does the following:

- **Eases the criteria for a group of physicians to qualify as a group practice. This change broadens the number of groups that can use the in-office ancillary services exception for referrals within the group.**
- **Provides more uniform definitions of the DHS.**
- **Allows physicians to receive payments based on a unit-of- service or unit-of-time basis, as long as the payments are fair market value and do not vary over time.**

(01/04/2001)

25. Q: Do the categories of DHS in the final rule differ from the categories in the proposed rule?

25. A: Yes. We have made changes in the following categories:

- **We have renamed radiology services and radiation therapy and supplies so that it now covers radiology and certain other imaging services, and we created a separate category for radiation therapy. The radiology category reflects the statutory requirement that it include certain non-radiology imaging services.**
- **We combined physical therapy, occupational therapy, and speech-language pathology services into a single category.**

(01/04/2001)

26. Q: How does Phase I provide more precise definitions of the DHS?

26. A: Phase I uses Current Procedural Terminology (CPT) codes and HCFA Common Procedure Coding System (HCPCS) codes in defining most of the DHS in order to establish bright lines. For the few remaining DHS, Phase I uses the usual Medicare definitions. (01/04/2001)

27. Q: What are HCFA Common Procedure Coding System (HCPCS) codes and Current Procedural Terminology (CPT) codes?

27. A: The HCPCS is a collection of codes and descriptors that represent procedures, supplies, products, and services that may be provided to Medicare beneficiaries and to individuals enrolled in private health insurance programs. These codes must be used in billing Medicare for Part B services and supplies. These codes are divided into three levels, two of which are used in the final rule:

- **Level I: Codes and descriptors copyrighted by the American Medical Association in its Current Procedural Terminology, Fourth Edition (CPT-4). These are 5-position numeric codes primarily representing physician services. (These codes are commonly referred to as CPT codes).**

- **Level II: These are 5-position alphanumeric codes representing primarily items and non-physician services that are not represented in the level I codes. (These codes are commonly referred to as HCPCS codes).**

(01/04/2001)

28. Q: Why is HCFA using CPT and HCPCS codes to define the DHS?

28. A: CPT and HCPCS codes are used to define certain DHS because commenters found that they had trouble understanding the narrative, descriptive terms used in the proposed definitions. Several commenters suggested that the use of CPT and HCPCS codes would greatly clarify the definitions of certain DHS, particularly the category that includes radiology services. (01/04/2001)

29. Q: How does Phase I incorporate the CPT and HCPCS codes?

29. A: The definitions of four of the DHS refer the reader to an Attachment that we published in the Federal Register along with Phase I. This document is called List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions. It identifies each of the individual CPT and HCPCS codes that comprise these DHS, and the list of codes defines the entire scope of the DHS category. The four DHS include:

- **Clinical laboratory services.**
- **Physical and occupational therapy and speech language pathology services.**
- **Radiology and certain other imaging services.**
- **Radiation therapy services and supplies.**

We will update the codes annually by providing a revised listing on the HCFA web site and by publishing the listing as an addendum to the annual final rule concerning payment policies under the physician fee schedule rule.

There are two DHS that are defined by HCPCS codes that are not included in the attachment. These are defined as including all the HCPCS level II codes associated with the category; we did not believe that they required individual listings. These two categories are:

- **Parenteral and enteral nutrients, equipment and supplies.**
- **Prosthetics, orthotics, and prosthetic devices and supplies.**

(01/04/2001)

30. Q: How do the physician referral law and Phase I relate to the anti-kickback statute?

30. A: The physician referral law (section 1877 of the Social Security Act), establishes a minimum threshold for acceptable financial relationships. Thus, potentially abusive financial relationships that may be permitted under section 1877 are addressed through other statutes that concern health care fraud and abuse, including the anti-kickback statute. The anti-kickback statute, section 1128B(b) of the Social Security Act, provides criminal penalties for individuals and entities that knowingly and willfully offer, pay, solicit, or receive bribes, kickbacks or other remuneration to induce business reimbursable by a Federal or State health care program, including Medicare. In certain instances, financial relationships that are permitted by section 1877 might merit prosecution under the anti-kickback statute. Conversely, conduct that may be prohibited by section 1877 may not violate the anti-kickback statute. (01/04/2001)

31. Q: Does this final rule apply to referrals by non-physicians, such as physician assistants and nurse practitioners?

31. A: In general, section 1877 of the Social Security Act, which focuses exclusively on referrals by physicians, does not apply to non-physician practitioners. However, if a referral made by a physician assistant or nurse practitioner (or other non-physician) is directed or controlled by a physician, we will treat the referral as an indirect referral made by the directing or controlling physician. (01/04/2001)

32. Q: Under the new regulations, is lithotripsy a designated health service?

32. A: The regulations treat lithotripsy the same as any other inpatient or outpatient hospital service. Although many commenters urged us to exclude lithotripsy from the definition of an inpatient or outpatient hospital service, we determined that there was no basis to differentiate lithotripsy services from any of the other services that may be provided under arrangements with hospitals, such as cardiac catheterization or vascular labs that are similarly situated. Moreover, excluding lithotripsy from the definition of inpatient and outpatient hospital services would not obviate the need for the urologist-owners of lithotriptors to structure their rental arrangements to comply with section 1877 of the Act, since the rental arrangement itself would create a financial relationship between the urologist-owners and the hospital. Unless the financial relationship (that is, the lithotriptor lease) fit into a compensation exception (such as the equipment rental exception), the urologists could not refer any Medicare or Medicaid patients to the hospital for any inpatient or outpatient services. (01/04/2001)

33. Q: Does that mean that physician-owned lithotriptors cannot be rented by hospitals?

33. A: No. For one thing, section 1877 does not prohibit any financial arrangement; it only prohibits physicians with a prohibited financial arrangement with an entity from referring Medicare or Medicaid patients to that entity for designated health services and it prohibits the entity from billing for those services.

More importantly, under the statute and regulations there are two exceptions that may apply: the equipment rental exception and the newly-created exception for fair market value arrangements. The regulations make clear that "per service" or "per use" rental or services payments are permitted, even for services performed on patients referred by the physician-owner, provided the rental or services payment is fair market value and does not take into account any Federal or private pay business generated between the physician and the hospital (and provided all other conditions of an exception are met). (01/04/2001)

34. Q: How does the hospital determine what is fair market value for a lithotriptor lease?

34. A: Because the prevalence of physician ownership of lithotriptors may distort pricing in the marketplace, we believe valuation methods that look to the prices charged by persons not in a position to refer to the hospital or that consider acquisition cost and rate of return are especially appropriate. We also are aware that some manufacturers of lithotriptors lease the machines to urologists on a "per use" basis with the urologists, in turn, leasing the lithotriptors to hospitals on a "per use" basis. In these circumstances, any disparity in the "per use" fee charged by the manufacturer to the urologists and the "per use" fee charged in turn by urologists to the hospital would call into question whether both sets of fees could be fair market value. (01/04/2001)

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